DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

October 18, 2002

3742 02 1:21

Marianne Robb
Manager, Regulatory Affairs
Mallinckrodt, Inc
675 McDonnell Boulevard
St. Louis, MO 63134

Re: Docket No. 01P-0252/CP1

Dear Ms. Robb:

This responds to your amended citizen petition, dated July 26, 2001, requesting that the Food and Administration (FDA) determine whether dextroamphetamine sulfate tablets, 15 milligrams (mg) were withdrawn from sale for reasons of safety or effectiveness.

The FDA has reviewed its records and determined that dextroamphetamine sulfate tablets, 15 mg were not withdrawn from sale for reasons of safety or effectiveness. This determination allows the FDA to maintain dextroamphetamine sulfate tablets, 15 mg in the "Discontinued Drug Product List" of the *Approved Drug Products with Therapeutic Equivalence Evaluations,* (the "Orange Book").

Enclosed is a copy of the *Federal Register* notice announcing the FDA's determination. If you require any further information, please do not hesitate to call me at 301-594-2041.

Sincerely yours,

Mary Catchings

Mary Catchings
Division of Regulatory Policy I (HFD-7)
Center for Drug Evaluation and Research

Enclosure

01P-0252 LET 2

using this survey questionnaire will aid FDA in assessing risks that may be associated with vaccine product usage that are not foreseen or apparent during the premarket notification and review process, so the agency may take appropriate public health or regulatory action including dissemination of this information as necessary and appropriate.

In the **Federal Register** of June 27, 2002 (67 FR 43323) FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Survey	No of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
"A Case-Control Study of HLA Type and T-Cell Reactivity to Recombinant Outer Surface Protein A and Human Leukocyte Function-Associated Antigen-1."	225	1	225	0.5	112.5

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA projects that there will be up to 75 case subjects recruited into this study with 3 control subjects recruited for each case subject, with a total maximum of 225 survey questionnaire respondents. FDA also projects a response time no greater than 0.5 hours per response. This estimate is based on previous results experienced with the instrument during enhanced surveillance followup of adverse events reported to VAERS. Respondents will only be contacted once during conduct of this study for the purposes of collection of vital information using this survey questionnaire.

Dated: October 11, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–26621 Filed 10–17–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01P–0252]

Determination That Dextroamphetamine Sulfate Tablets, 15 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that dextroamphetamine sulfate 15-milligram (mg) tablets (formerly marketed by Lannett Co., Inc.) were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for dextroamphetamine sulfate 15-mg tablets.

FOR FURTHER INFORMATION CONTACT: Mary E. Catchings, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20855, 301–594–2041.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (the 1984 amendments) (Public Law 98–417), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA sponsors must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the "listed drug," which is a version of the drug which was previously approved. Sponsors of ANDAs do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA). The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the "Approved Drug Products With Therapeutic Equivalence Evaluations," which is generally known as the "Orange Book." Under FDA's regulations, drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

Under 21 CFR 314.161(a)(1), the agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved. FDA may not approve an ANDA that does not refer to a listed drug.

Dextroamphetamine sulfate tablets, 15 mg, are the subject of approved ANDA 85–652 held by Lannett Co., Inc. Dextroamphetamine sulfate tablets are indicated for narcolepsy and for attention deficit disorder with hyperactivity. Lannett Co., Inc.'s, dextroamphetamine sulfate 15-mg tablets are currently listed in the "Discontinued Drug Product List" section of the Orange Book.

On May 17, 2001, Mallinckrodt, Inc., submitted a citizen petition (Docket No. 01P–0252/CP1) to FDA under 21 CFR 10.20 and 10.30. The petition, as amended July 26, 2001, requested that the agency determine that dextroamphetamine sulfate tablets, 15 mg, were not withdrawn from the market for reasons of safety or effectiveness.

The agency has determined that dextroamphetamine sulfate tablets, 15 mg, were not withdrawn from sale for reasons of safety or effectiveness. There are several grounds for FDA's finding. First, there are drug products containing 15-mg dextroamphetamine sulfate being marketed today. Although these drug products are extended release products rather than immediate release products, FDA has concluded that this difference does not affect the product's safety. Second, the petitioner identified no data or other information suggesting that dextroamphetamine sulfate tablets, 15 mg, were withdrawn from sale as a result of safety or effectiveness concerns. Third, Lannett Company, Inc.,